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The development and validation of the CARE Burn Scale - Adult Form: a Patient Reported Outcome Measure (PROM) to assess quality of life for adults living with a burn injury

Abstract

Introduction: Patient Reported Outcome Measures (PROMs) identify vital information about patient needs and therapeutic progress. This paper outlines the development and validation of the CARE Burn Scale - Adult Form: a PROM that assesses quality of life in adults living with a burn injury.

Methods: 11 patient, 10 family member and 4 health professional interviews, and a systematic review were conducted to inform the development of a conceptual framework and a draft measure. Cognitive debriefing interviews conducted with 3 adult burn patients, 1 family member and 8 health professionals provided feedback to ascertain content validity of the measure. The measure was then field tested with 304 adult burn patients. Rasch psychometric analysis was conducted for scale reduction, and traditional psychometric analyses provided a comparison with other measures. Further psychometric testing with an additional 118 adult burn patients tested the shortened CARE Burn Scale in relation to other quality of life PROMs.

Results: The conceptual framework outlined 14 domains; 12 of which fulfilled Rasch and traditional psychometric analyses. Two individual scales did not fulfil the Rasch criteria and were retained as checklists. Individual CARE Burn Scales correlated moderately-to-highly with other quality of life scales measuring similar constructs, and had low-to-no correlations with dissimilar constructs and the majority of sociodemographic factors, indicating evidence of concurrent and divergent validity.

Conclusions: The CARE Burn Scale – Adult Form can help identify patient needs and provides burns-specialist health professionals with a tool to assess quality of life and therapeutic progress after a burn event and related treatment.

Keywords: Patient-Reported Outcome Measure; PROM; Adult; Burn; Scar; Quality of Life

Introduction

In the UK, approximately 250,000 individuals sustain burn injuries every year, with 7,634 patients requiring specialist treatments in 2011 [1, 2]. The needs of burn patients are complex and wide-ranging. Burn wounds and scarring can cause severe pain and itching and limit range of movement [3, 4]. These factors, along with potentially significant time spent attending scar management, physiotherapy and other clinical appointments, can also impact an individual's ability to engage with work and activities of daily living [5].

A number of psychosocial difficulties such as depression [6-11], anxiety [6, 9, 12, 13], difficulties sleeping [14], and trauma symptoms [5, 6, 8, 9, 15] can also accompany the physical impact of a burn. Patients with burn scarring can also encounter unwanted questions or staring from others which can lead to avoidance of activities which could draw attention to their scars, fear of being judged negatively by others, low social self-esteem and withdrawal from romantic relationships [16-18]. Consequently, social support from friends, family and health professionals is paramount when adapting to the impact of a burn [19, 20].

Given the complex and varying needs of burn patients, it is essential that health professionals are able to comprehensively assess post-burn adjustment, in order to identify individual support needs. Whilst many adjust well [9, 21], and some report posttraumatic growth following the injury [22], others experience significant difficulties [23]. For some, psychosocial adjustment is harder to manage than the physical symptoms [24].

Furthermore, psychosocial difficulty is not predicted by the size, location, or depth of a burn [25] and many patients encounter new challenges as they progress through their treatment and recovery [5]. It is, therefore, important to assess the needs of all patients rather than focussing on those with more physically serious or visible injuries, and not to focus solely on the acute recovery period.

However, psychosocial health professionals working in UK NHS (National Health Service) Burn Services, often lack time and resources to assess all patients, or rely on information from staff who do not have specialist training when deciding who would benefit from psychosocial support [5]. Patient Reported Outcome Measures (PROMs) offer a potential solution to issues of assessment in burn services. PROMs, which are standardised, rigorously tested health-related questionnaires, enable health professionals to identify the needs of their patients, and assess their therapeutic progress throughout the treatment pathway [26]. Furthermore, communicating the status of one's own health can be an empowering experience for patients; putting them at the centre of their own care [27]. Although the use of PROMs within the UK was recommended by The NHS Next Stage Review [28], the National Burn Care Review concluded that PROMs are not consistently used within UK Burn Services and identified a lack of PROMs designed to assess the needs of burn patients being treated within this system [29]. For this reason, the need to develop burn-specific UK

PROMs and the importance of rigorous outcome measurement within UK burn care have been highlighted [1, 27].

A recent systematic review of PROMs used in adult burn research identified 77 different PROMs being used, however only four were burn-specific [30]. Whilst generic PROMs can be useful for detecting general health outcomes, condition-specific PROMs often have better face validity and can be more sensitive to condition-specific health needs and detecting therapeutic changes [31]. Although the level of psychometric evaluation was considered strong overall, Griffiths et al's review concluded that most PROMs had not been validated with an adult burn population, and only a small number had been developed in collaboration with adult burn patients.

Positively, a small number of validated burn-specific PROMs, assessing quality of life in adult burn patients, are available. These include the Burn-Specific Health Scale-Abbreviated (BSHS-A) [32] and Burn-Specific Health Scale-Brief (BSHS-B) [33], the Adult Burn Outcome Questionnaire Short Form (ABOQ) [34], the Young Adult Burn Outcome Questionnaire (YABOQ)[35], the Brisbane Burn Scar Impact Profile (BBSIP) for Adults [36] and the Life Impact Burn Recovery Evaluation (LIBRE) Profile [37]. However, there are currently no PROMs which have been designed for, or developed in collaboration with, adult burn patients in the UK. Additionally, current PROMs do not include all aspects of quality of life affected by burns (e.g. positive growth) or both the wound and scar phases after injury. This has led health professionals to rely on large batteries of different measures, which can be time consuming and burdensome for patients [5]. In summary, it is important that Burn Services in the UK have access to a quality of life PROM for adults affected by burns which assesses all aspects of burn injuries, and can be used at any stage of recovery.

The present study therefore followed the PROM development guidelines from the Scientific Advisory Committee of the Medical Outcomes Trust (2002) [38] and Cano et al [39], to rigorously develop and psychometrically evaluate a burn-specific PROM to assess the needs of UK adult burn patients.

Methods

All necessary University and NHS ethics approvals were obtained.

The CARE Burn Scale - Adult Form was developed following an established development and validation process, identified as the gold standard for developing and evaluating PROMs [38, 39]. This involved item generation (developing a conceptual framework using a literature review, qualitative interviews with patients and expert opinion), item reduction (using psychometric criteria such as Rasch analysis) and psychometric evaluation (using psychometric criteria).

Stage 1.1: Conceptual framework development

The conceptual framework of a PROM outlines the concepts/domains that it measures and the scale items are then developed based on this framework [38]. Historically, 'top down' methods have often been used in which the conceptual framework and related items are developed based on reviews of the literature or existing measures or conceptual frameworks [40]. Developing injury-specific measures (such as burn-specific PROMs) using these 'top down' methods alone and not involving the patient population that the PROM is intended for, increases the likelihood that key experiences related to the impact of the

injury on health outcomes will be missed [41]. This in turn can reduce the content validity and the potential responsiveness of the PROM if it fails to measure key health domains that are important to the patient population [40].

More recently, a number of PROM development guidelines recommend using qualitative interviews or focus groups with patients to inform the conceptual framework and related items to increase the content validity of the PROM being developed [38, 42, 43]. The Cochrane Handbook of Systematic Reviews [42] in particular recommends that the conceptual framework (i.e. the outline of the domains that a PROM measures) should be elicited from qualitative interviews with patients from the target population (in this case adult burn patients) and patients should be involved in generating the items that each domain measures to ensure that all relevant aspects of the domain are measured. The involvement of patients at the conceptual framework and item development stage is deemed essential to the content validity of the measure [42].

Similarly, Cano et al [39, 44, 45] recommend that the conceptual framework of a PROM should be based on in-depth qualitative interviews with the target population, expert opinions and a review of the literature. The current study followed this method to develop the conceptual framework and PROM items in the CARE Burn Scale – Adult Form.

Semi-structured interviews were conducted with adult burn patients and burns-specialist health professionals to explore, in-depth, patients' experiences of living with a burn injury and its impact on quality of life. Recruitment aimed to include patients with different types of burn and from different age groups. Interviews took place face-to-face and over the telephone between April 2013 – October 2013. They were tape recorded, transcribed verbatim and subjected to a thematic analysis [46]. These findings informed a conceptual

framework to outline the key aspects of well-being that are influenced when living with a burn injury, and the domains that the CARE Burn Scale would measure.

Stage 1.2: Item generation, initial scale formation and pre-testing

An extensive list of potential items was created for each domain in the conceptual framework, based on the patient interview data. When possible, patients' own words or phrases were incorporated to increase the content validity of the items. A systematic review of patient reported outcome measures used in adult burn care research was also conducted [30] and from this review relevant quality of life scales were obtained and reviewed. Any new items identified in these scales that were not discussed in the interviews were added to the relevant CARE Burn Scale domain. Lastly, psychologists, counsellors and nurses from NHS Burn Services across the UK reviewed the draft measure and provided feedback to ensure it was as comprehensive as possible, acceptable to its potential users and suggested new items that were thought missing.

Cognitive debriefing interview techniques, a recommended part of the PROM development process [44, 47], were then conducted with adult burn patients who were asked to review the draft scale to explain their understanding of the items, identify any that were unclear or hard to understand, provide feedback on the response categories, and suggest any new items that they felt were missing [45].

Stage 2: Item reduction

Field-test versions of the CARE Burn Scale were handed out in burn clinics and posted to adult burn patients from 11 NHS Burn Services throughout the UK. Eligible participants were

adults aged 18 and over who had sustained a burn injury, had received treatment from an NHS Burn Service, and were able to read English in order to complete the questionnaire.

Rasch Measurement Model and Analyses

For the purpose of the Rasch Analyses, the raw scores were transformed into logits and then translated into a linear scoring system, using summated scales as described in Appendix B. The Rasch measurement model [48-50] and analyses [51-53] were used for item reduction using RUMM2030 [54]. The data collected for each domain of the conceptual framework was analysed against the Rasch measurement criteria described below during the item reduction phase.

Item fit statistics

Rasch analysis involves assessing whether the observed data is consistent with the responses predicted by the Rasch mathematical model. Two indicators were examined: 1) item-trait interaction where a non-significant chi-square value ($p > 0.05$) indicates negligible deviation between observed data and expectations of the model); 2) the standardised residual, for each item in the range -2.5 to +2.5 indicates good fit, and should also have non-significant chi-square values (Bonferroni adjusted significance level of 0.01).

Person separation index (PSI)

The PSI measures whether the measurement of patients in this sample are reliably separated. Higher scores reflect stronger reliability. The value of 0.7 indicated the possibility to distinguish at least two groups of patients. The PSI is similar to Cronbach's alpha which is commonly used to measure reliability [55, 56].

Local dependency

For each pair of items within a scale, a residual correlation >0.3 above the mean residual correlation (of all item pairs for that scale) [57] indicates a problem with fit, suggesting the existence of extraordinary association within the set of items.

Unidimensionality

Unidimensionality assumption was checked by application of Smith's procedure [58] based on paired t-tests to see if the person estimates derived from most diverse subsets of items are significantly different. Unidimensionality is supported if the percentage, or the lower bound of the 95% binomial confidence interval, of significant t-tests ($p < 0.05$) is less than 5%.

Differential Item Functioning

To assess the extent to which item parameters remain invariant across different groups of patients we used Differential Item Functioning analysis (DIF) [59]. We compared item difficulties given the level of the trait across the following: age (split based on median: ≤ 41 , >41), gender, ethnicity (White-British, Other), cause of burn (flame or liquid, contact, electricity, chemical, acid or other), wound healing status (burn scar, burn wound, both wound and scar, no wound or scar, other) and body part affected (usually visible to others [e.g., head, neck, face, hands] or non-visible [e.g., back, legs, bottom]). By this check we explored the issue of possible bias that might be resulting in misfit of the data to model. Uniform and non-uniform DIF were investigated graphically (inspection of item characteristic curves (ICCs) for different groups) and by results of analysis of variance (Bonferroni adjusted significance level of 0.05).

Targeting and item locations

Distributions of item and person locations were graphically compared to determine whether they covered more or less on the same areas of Rasch continuum. Large floor and ceiling effects would indicate the existence of the problem.

Item thresholds

For each item, the use of response categories scored with successive integer scores indicated a continuum of increasing impact. This assumption was tested by ordering the thresholds (or points of crossover between two adjacent response categories) specified by the Rasch analysis.

Traditional psychometric analysis (Classical test theory)

Traditional psychometric analysis via classical test theory (CTT) were also conducted on the data to show how the scale operates based on the CTT criteria: Cronbach's alphas (for each scale domain) and item-total correlations. Analyses were undertaken using IBM SPSS Statistics 23 [60] .

Stage 3: Further psychometric evaluation

The final version of the CARE Burn Scale was then tested in comparison to other validated quality of life questionnaires in a different sample of adult burn patients to ascertain evidence of concurrent and discriminant validity, following recommended PROM development guidelines and criteria [61]. Questionnaires were handed out in burn clinics and posted out to adult burn patients recruited from 11 NHS Burn Services throughout the UK. Eligible participants were adults aged 18 and over who had sustained a burn injury and

received treatment from an NHS Burn Service. Patients needed to be able to read English fluently in order to complete the questionnaire.

All statistical analyses were performed in Stata v.15.1 [62]. In addition to tests of data quality and scaling assumptions, the following properties relating to validity and reliability were examined:

1. Concurrent and discriminant validity: The final version of the CARE Burn Scale – Adult Form was compared with existing health PROMs which measure similar constructs (the Burn Specific Health Scale Abbreviated (BSHS-A) [63], EQ5ED [64], PTSD CheckList – Civilian Version (PCL) [65] and the Post-traumatic Growth Inventory [66]. It was hypothesised that the CARE Burn Scale – Adult Form subscales would have moderate/high significant correlations with related constructs and low/no significant correlations with dissimilar constructs. Criteria were used as guides in terms of the magnitude of correlations, as opposed to pass/fail benchmarks (high correlation, $r > 0.70$; and moderate correlation, $r = 0.30$ to 0.70).

Specifically, regarding the various subscales of the CARE Burn Scale – Adult Form (described in the results section, below), it was hypothesised that:

- *Wound/Scar Discomfort* and *Physical Well-being* would moderately correlate with the BSHS Physical Health scales.
- *Social Situations* would moderately correlated with the BSHS Social Health total score.
- *Friend Support* would moderately correlate with the BSHS Social Friends subscale.

- *Work Life and Family Support* would moderately correlate with the BSHS Social Health total score.
- *Wound/Scar Dissatisfaction* would moderately correlate with the BSHS Body Image subscale.
- *Trauma Symptoms, Negative Mood and Self-worth* would moderately correlate with the BSHS Mental Health total score and BSHS Mental Affect subscale.
- *Intimacy* would moderately correlate with the BSHS Social Sexual subscale.
- The Post Traumatic Growth Inventory would moderately correlate with *Positive Growth* and have low/no correlations with the other CARE Burn Scales since they are dissimilar constructs.
- *Trauma Symptoms* would moderately correlate with the PTSD CheckList – Civilian Version (PCL).
- The EQ-5D-5L would have low/moderate correlations with the individual CARE Burn Scale sub-scales since it is a general quality of life measure.

Traditional psychometric measurement properties were also examined: acceptability (percentage of missing data; <10%), and reliability (Cronbach's alpha coefficients; >0.70), and acceptable item–total correlations; >0.30).

The relationship between CARE Burn Scale subscales and sociodemographic variables (age, gender, time since burn, ethnicity, marital status and cause of burn) were also examined using regression analyses to determine the extent to which scores were influenced by these variables.

Results

Stage 1.1. Conceptual framework formation

Eleven adult burn patients (4 female, 7 male, aged 27 to 78 (M=51.90, SD: 18.68) (Table 1) and ten of their family members (7 partners, 2 mothers and 1 daughter, 7 female, 3 male, aged 42 to 78, M: 57.00, SD: 13.09) were interviewed. Four clinical psychologists who worked with adults with a burn were also interviewed (in depth analysis of the health professionals' interviews is reported in Guest et al, 2018 [5] and patient interview analysis is reported in Griffiths [67]). Thematic analysis identified a range of themes which reflected patients' experiences of living with a burn injury and its impact on quality of life. Informed by these interviews, expert opinions and the systematic review [30]; 14 key domains formed the conceptual framework of adult burn patients' experiences of living with a burn (see Figure 1):

1. *Wound/Scar Discomfort*: the extent to which patients feel discomfort or pain in relation to their burn wound/scar.
2. *Physical Well-being*: patients' physical health and their physical abilities.
3. *Wound/Scar Treatment*: the extent to which patients feel bothered by a range of different wound/scar treatments such as dressing/bandage changes, washing and dressing and physiotherapy exercises.
4. *Social Situations*: patient confidence in challenging social situations in which other people may look, touch or ask questions about their burn wounds/scarring.
5. *Avoidance Behaviours*: the extent to which patients avoid looking at their burn or avoid activities or situations because of how their burn wounds/scars look.
6. *Self-worth*: the extent to which a patient has positive feelings about themselves.

7. *Negative Mood*: the extent to which a patient reports low/negative mood.
8. *Wound/Scar Dissatisfaction*: how bothered patients feel about the look of their burn wound/scarring.
9. *Work Life*: patients' perceptions of the quality of their work life.
10. *Family Support*: patients' perceptions of the quality of their family relationships.
11. *Friend Support*: patient perceptions of the quality of their friendships.
12. *Intimacy*: the extent to which patients' feel attractive to others and confident about showing their burn wounds/scars in intimate situations.
13. *Trauma Symptoms*: negative psychological and behavioural symptoms related to the patient's burn injury, such as flashbacks, bad dreams and anxiety.
14. *Positive Growth*: the extent to which patients report positive outcomes/personal development after living with a burn injury.

*INSERT TABLE 1 AND FIGURE 1

Stage 1.2: Item generation, initial scale formation and pre-testing

Initial items (n = 110) were generated, covering all 14 domains of the conceptual framework. Cognitive debriefing interviews were then conducted with 3 adult burn patients and 1 family member, and feedback was also obtained from 7 health professionals (4 clinical psychologists, 1 counsellor, 1 psychotherapist, 1 physiotherapist) and 1 international PROM development expert. This resulted in minor changes to items (changes to wording, providing more burn-specific examples, more simple language) and a further 99 items being added to the existing domains, resulting in 209 items in the scale that was field tested.

The domains in which increasingly higher scores reflect increasingly poorer outcomes are:

Burn Wound/Scar Discomfort, Wound/Scar Treatments, Wound/Scar Dissatisfaction, Avoidance Behaviours, Trauma Symptoms, Negative Mood. The domains in which

increasingly higher scores reflect increasingly better outcomes are: *Physical Well-being, Confidence in Social Situations, Friendships, Family Life, Work Life, Intimacy, Self-Worth, Positive Growth.*

Stage 2: Item reduction phase

Sample

A total of 304 participants completed the CARE Burn Scale – Adult Form. Participant characteristics are shown in Table 2. The largely supported rule of thumb is that in order to perform an accurate and precise Rasch analysis to >99% confidence and with item calibrations within ± 0.5 logits, the advised sample size is 250[68] .

Item reduction

The raw scores were transformed into logits for the purpose of Rasch analyses, which are translated into a linear scoring system (see Appendix).

Of the 14 scales tested, a Rasch solution was found for 12 (Table 3). This was not the case for the *Discomfort with Burn Wound/Scar Treatment* and *Avoidance Behaviours*, which are reported as checklists. For *Discomfort with Burn Wound/Scar Treatment*, the items occupied mostly the same space on the Rasch continuum, meaning that there is no requirement for multiple items and thus a scale cannot be formed. For *Avoidance Behaviours*, multiple items had multiple issues with combinations of model fit, local independence and differential item

functioning on gender and scar visibility. Despite all various attempts to find a solution, none could be found to satisfy the criteria of the Rasch measurement model.

Overall, using the Rasch Measurement Model and Analyses (previously described in the method section), the initial 194 items across the 12 scales were reduced to 45 items (see Table 3). Scale reliability was generally supported by high PSI, with only *Low Mood* and *Positive Growth* exhibiting $PSI < 0.70$ (0.62 - 0.69 respectively). Fit to the Rasch model was good, with all item-trait interactions non-significant and no items with fit residuals out of range or presenting significant X^2 values. All final scale solutions contain no items with reversed thresholds. However, all but *Positive Growth* required response thresholds to be collapsed for this to be the case. For *Wound/Scar Discomfort*, *Wound/Scar Dissatisfaction*, *Trauma Symptoms* and *Low Mood*, the second and third categories were collapsed. For *Physical Well-being*, *Social Situations*, *Friend Support*, *Work Life*, *Family Support*, *Self-worth* and *Intimacy*, the third and fourth categories were collapsed. All pairs of items within each scale had a residual correlation less than 0.3 above the mean residual correlation (of all item pairs for that scale), supporting local independence amongst items. The vast majority of items did not exhibit DIF, suggesting that items remain invariant across different groups of patients. Unidimensionality was confirmed via Smith's procedure [58] for all 12 scale solutions.

Despite finding 12 solutions, all had gaps in the person location and item threshold distributions, meaning that it is not possible to wholly reflect the range of the continuum (Appendix A). *Physical Well-being*, *Social Situations*, *Friendship*, *Work Life*, *Family Life*, *Burn Wound/Scar Dissatisfaction* and *Trauma Symptoms* had ceiling effects in their person distributions. Also *Social Situations*, *Self-worth* and *Low Mood* had items with DIF issues.

However the evidence for these DIF issues is weak (p-value just less than the $\alpha = 0.05$ Bonferroni-corrected level) but are reported for full disclosure.

See Appendix B for a list of the final scale items.

Traditional psychometric analyses (Classical test theory)

All scales with Rasch solutions passed criteria for acceptability, reliability and validity (Table 3): Cronbach's $\alpha > 0.80$ and all item-total correlation coefficients > 0.70 .

Checklists

Based on theoretical insight, scales for which a Rasch model solution could not be found were kept (with all original items) as checklists. For all items of the *Wound/Scar Treatment* scale, 'Not a lot' was the most commonly endorsed category. Similarly for items of *Avoidance Behaviours*, 'Never' was the most commonly endorsed category (Table 4).

*INSERT TABLES 2, 3 AND 4 HERE

Stage 3: Further psychometric evaluation

Sample

Adult participants ($n = 118$; 78 women, 37 men, 3 gender not provided), aged 32-86 years (mean: 55.5 years, SD: 15.4 years) took part (see Table 5). A sample size of $n = 95$ or larger will have in excess of 95% power to reject a correlation of 0.3 or lower compared to a correlation of 0.6 or higher. For sample sizes on $n = 115$ or larger, the asymmetric 95% confidence interval for correlation coefficients greater than 0.3 will have an absolute margin of error of no more than 0.166.

*INSERT TABLE 5 HERE

Traditional Psychometric Analyses

Table 6 and 7 provide results of the traditional psychometric analysis. All scales exceeded criteria for validity and reliability. Scale reliability was supported by high Cronbach's alpha coefficients (>0.80), and appropriate item-total correlations (range of means, 0.62 to 0.80). Level of missing data was higher than 10% for 15 out of 45 items and tended to occur in the same domains (*Work Life*, *Intimacy*, *Trauma Symptoms* and *Social Situations*). Missing data on these items ranged from 12%-42%. A comparison of the results with and without missing data showed that the Cronbach's alphas remained unchanged which indicates that the missing data did not bias the results (Table 6).

Scale validity was supported by the correlations between the CARE Burn Scale sub-scales and the other validated quality of life/health psychometric measures (Table 8). Hypotheses relating to correlations between CARE Burn Scale subscales, the Burn Specific Health Scales [63], the EQ-5D-5L [64], PTSD CheckList – Civilian Version (PCL) [65] and the Post Traumatic Growth Inventory [66] were widely supported through moderate correlations with related constructs and low/no correlations with dissimilar constructs.

As predicted, the CARE Burn Scales correlated moderately/highly with many of the Burns Specific Health Scales. In particular, *Wound/ Scar Discomfort* and *Physical Well-being* moderately correlated with the all of the BSHS Physical Health subscales, *Social Situations* moderately correlated with the BSHS Social Health total score, *Friend Support* was highly correlated with the BSHS Social Health total score and the BSHS Social Friends subscale, *Work Life* and *Family Support* were moderately correlated with the BSHS Social Health Total Score. *Wound/Scar Dissatisfaction* was highly correlated with the BSHS Body Image

subscale, *Trauma Symptoms* moderately correlated with the BSHS Mental Health total score and the BSHS Mental Affect subscale, *Negative Mood* was highly correlated with the BSHS Mental Health total score and the BSHS Mental Affective subscale. However, *Self-worth* did not significantly correlate with any of the BSHS Mental Health or Affect subscales and *Intimacy* did not correlate with the BSHS Sexual subscale which was not consistent with the predicted hypotheses.

As predicted, the Post Traumatic Growth Inventory showed significant moderate correlations with *Positive Growth* but not with any of the other CARE Burn Scale sub-scales. The PTSD CheckList – Civilian Version (PCL) was found to moderately correlate with *Trauma Symptoms* and *Negative Mood*. The EQ-5D-5L moderately correlated with all individual CARE Burn Scales apart from *Family Support*, *Self-worth*, *Intimacy* and *Positive Growth*.

***INSERT TABLES 6, 7, 8 AND 9 HERE

Regression analysis identified significant relationships between 6 of the individual CARE Burn Scale sub-scales and sociodemographic variables (i.e. age, time since burn, gender, ethnicity, marital status and cause of injury) (Table 9). There was a significant effect of cause of burn, with non-liquid injuries being significantly associated with greater wound/scar discomfort compared to liquid injuries. Time since burn was significantly associated with greater work well-being. Women and those sustaining non-liquid burn injuries were more likely to report greater wound/scar dissatisfaction. Non-liquid injuries were also significantly associated with more negative mood and time since injury was associated with greater

positive growth. However, since the majority of regression coefficients (66/72) were non-significant, this provides evidence of discriminant validity.

***INSERT TABLE 9 HERE

Discussion

The CARE Burn Scale – Adult Form was developed and validated with adult burn patients who had received treatment in the NHS Burn Service. They played a key, fundamental role in the development of this new PROM, informing item generation and reviewing and commenting on draft versions of the scale. The CARE Burn Scale - Adult Form therefore reflects key experiences that are pertinent to the quality of life of those living with a burn injury. Importantly, they highlighted the need to include both the wound and scar stages of injury recovery, and to ensure that the PROM could recognise trauma symptoms, avoidance behaviours, difficulties with wound/scar treatments, as well as positive outcomes and growth after living with a burn injury. The CARE Burn Scale – Adult Form is therefore the first burn-specific quality of life PROM to include reference to both the wound and scar stage of recovery and additional domains not captured in existing burn-specific PROMs.

The 12 scales with Rasch solutions showed good scale reliability was generally supported by high PSI values, and fit to the Rasch model was good. Evidence of reliability and validity based on traditional psychometric analyses was identified, as was concurrent and discriminate validity with other measures and sociodemographic factors. Overall, these

findings indicate that the CARE Burn Scale – Adult Form is a valid and reliable scale to measure quality of life for adults living with a burn injury.

The item reduction stage was led by Rasch analysis which permits individual patient and subsample level measurement and produces interval level data that allows measurement invariance to be tested and valid total scores to be created. These increase the potential for the PROM to identify clinical change which will be of benefit to clinicians and researchers alike [69]. Burns research is increasingly using Rasch analysis in PROM development/validation papers, such as the Patient and Observer Scale (POSAS) and Lower Limb Index [70] [71]. Researchers developing new PROMs for use in adult burn care should consider using Rasch to ensure that the PROMS they develop are suitable for measuring the health of both individual patients and subgroups.

Comparing the CARE Burn Scale- Adult form with existing burn-specific PROMs

The CARE Burn Scale – Adult Form does cover domains that some existing burn-specific PROMs also measure such as *Wound/Scar Discomfort* [34, 35], *Physical Abilities* [32-35], *Confidence in Social Situations* [34, 35, 37], *Friendships* [32-35, 37], *Family* [32-35, 37], *Work* [33-35, 37], *Wound/Scar Dissatisfaction* [32-35], *Intimacy* [32-35, 37] and *Negative Mood* [32-35].

However, the CARE Burn Scale – Adult Form has the advantage of including unique domains which are not measured by existing PROMs (such as the Abbreviated Burn Specific Health Scale (BSHS-A) [32], the Burn Specific Health Scale – Brief (BSHS-B) [33], Young Adult Burn Outcome Questionnaire (YABOQ) [35], the Adult Burn Outcome Questionnaire (YABOQ) Short Form [34], the Coping with Burns Questionnaire [72] and the Life Impact Burn Recovery Evaluation (LIBRE) [37]). These unique domains are: *Trauma Symptoms* (i.e. feeling upset, short tempered, experiencing bad dreams or flashbacks/vivid

memories), *Avoidance Behaviours* (i.e. avoiding looking at or touching burn wounds/scars, covering up wounds/scars or avoiding certain social activities because of their wounds/scars), *Self-Worth* (i.e. feeling confident, happy), *Wound/Scar Treatments* (i.e. whether treatments such as dressing changes, creaming/massage and physiotherapy exercises bother patients) and *Positive Growth* (i.e. life being more meaningful or feeling a better person after a burn injury). Using in-depth interviews with patients and health professionals to inform the conceptual framework and PROM items, rather than relying on existing PROMs or conceptual frameworks, led to these additional new domains which other scales do not cover. This further highlights the benefit of in-depth interviews when developing new PROMs to ensure that the scale measures the breadth of health outcomes that are most important to patients themselves [42].

Another advantage of the CARE Burn Scale – Adult Form is that it is freely available to download (via www.careburnscales.org.uk) for research and clinical purposes. Users are able to score the data themselves using the scoring sheets downloadable from the same website.

Limitations

Men typically outnumber women in the prevalence of burn injuries [2]. Yet there was a fairly even gender split in the Stage 2: Item reduction study. This might be explained by the fact that the data collection was part of a research project rather than routine clinical audit; women are significantly more likely to take part in research than men [73]. In the current study patients were simply invited to take part and were responsible for returning their questionnaire in the mail, or completed it online. Staff were not responsible for

motivating/encouraging participants to take part or for collecting questionnaires, which is a different process to data collection in clinical audit which burn prevalence statistics are based on. The common gender differences in research participation may therefore have influenced the gender spilt in this study. Furthermore, the regression analysis showed that gender did not have a significant effect on any domains of the CARE Burn Scale, apart from *Wound/Scar Dissatisfaction* which showed women were more likely to be dissatisfied with their scarring compared to men. This is a typical finding in burns research [74]. Therefore, the less typical gender spilt in the sample did not have a significant effect on the overall findings of the study.

The burn aetiology in this study was comparable to other studies with adult burn patients in the UK; the current had 20.6% flame injuries compared to 21.12% reported by Stylianou et al (using the UK IBID database for adult injuries that occurred from 2003- 2011) [2]. The percentage of scald/liquid injuries was higher in the current study (44.8%) compared with 33.29% reported by Styliou et al, but since women are more likely to experience scalds compared to flame injuries, the higher rates of scald injuries in our sample could be related to our more even gender spilt compared to the male bias typical in burn injuries more generally [2].

Another limitation of this study is the level of missing data identified in phase 3. Missing data is very common in questionnaire design studies and when collecting data in healthcare services, where less than 10% missing data is not thought to bias results [75, 76]. In the current study, the majority of items had less than 10% missing data, but for 15 out of 44 items this was 12-42% (mostly 10% - 15%). However two domains (*Work Life* and *Intimacy*) showed higher levels of missing data. This is not surprising since many adults delay returning

to work after a burn and some might not feel comfortable answering questions about their intimate lives. A comparison of the Cronbach's alphas for each individual CARE Burn Scale using datasets with and without missing data indicated a negligible impact of missing data on the reliability of the scales and the dataset with missing data was therefore retained. In phase 3, participants completed a number of other PROMs at the same time as the CARE Burn Scale, therefore missing data might reflect patient burden or fatigue from the longer survey length. Future research will test the final version of the CARE Burn Scale – Adult Form without the inclusion of other quality of life scales to gain a more accurate record of the level of missing data expected when completing it in routine clinical practice or research.

As with all psychometric scale development research, further ongoing validation work is needed. Test-retest reliability and responsiveness data are required to further validate the findings and explore the reliability of the CARE Burn Scale – Adult Form and its ability to detect clinical changes over time. This is necessary in order that suitably robust measures are available for longitudinal cohort studies within burns.

The CARE Burn Scale reported in this paper is only valid for adult burn patients. However this scale is part of a suite of PROMs being developed by the authors, including measures for use in burn care with children under 8 years of age (parental report), young people aged 8-17 years and parents [77-79]. Additionally, the CARE Burn Scale – Adult Form, has been tested with a UK population. Additional validation studies are warranted if they are to be used elsewhere, translation studies are needed if they are to be used with non-English speaking patients, and their value as a tool that can assess patient reported outcomes in different cultures needs to be explored [80].

Conclusions

The CARE Burn Scale – Adult Form measures key issues that adult patients have identified as being important to their well-being and quality of life after a burn injury. It was rigorously developed using gold standard guidelines and criteria for the development and review of patient reported outcome measures. The CARE Burn Scale – Adult Form is now available for clinical and research use to identify patients’ needs and therapeutic progress, conduct service evaluation, and compare outcomes at different burn centres (see www.careburnscales.org.uk to access the full set of CARE Burn Scales).

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